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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/684,149 | 10/10/2003 | James W. West | 02-17 | 5157 |

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| EXAMINER | |
|---|---|
| SCHWADRON, RONALD B | |

| ART UNIT | PAPER NUMBER |
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| 1644 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/684,149 | WEST ET AL. | |
| | Examiner | Art Unit | |
| | Ron Schwadron, Ph.D. | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,9-11 and 18-21* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9-11,18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/20/07 and 4/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election of the species mammalian and polyhistidine in the response filed 4/14/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

2. Claim 19 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions or species , there being no allowable generic or linking claim. Election was made without traverse in the response filed 4/14/08.

3. Claims 1-3,9-11,18,20,21 are under consideration.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1,2,3,9,18,20,21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed peptides.

The instant claims appear to encompass mutants and variants of TACI as well as TACI derived from any animal species. The specification discloses the amino acid sequence of a single known human TACI. The identity of mutants and variants of TACI

as well as TACI derived from other species is not disclosed in the specification or revealed in cited prior art and is unpredictable. The instant claims appear to encompass mutants and variants of trimerizing domains from Heat Shock Binding Protein-1 as well as Heat Shock Binding Protein-1 derived from any animal species. The specification discloses the amino acid sequence of a single known human Heat Shock Binding Protein-1. The identity of mutants and variants of Heat Shock Binding Protein-1 as well as said peptide derived from other species is not disclosed in the specification or revealed in cited prior art and is unpredictable.

Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals

appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, there are thousands of different mammalian species. While applicant refers to the "many species of TACI" disclosed in Bulow et al., Bulow et al. disclose ***two*** species of TACI (aka human and murine). Thus, the circumstances are virtually the same as per the Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). Regarding applicants comments about isolating other TACIs from other species, the Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. The previously pending rejection of claims 1,2 under 35 U.S.C. 102(e) as being anticipated by Ashkenazi et al. (US 2006/0073146) for the reasons elaborated in the previous Office action is withdrawn in view of the amended claims .

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. The previously pending rejection of claims 1-3 under 35 U.S.C. 103(a) as being unpatentable over Ashkenazi et al. (US 2006/0073146) in view of Rixon et al. (US 2003/0103986) is withdrawn in view of the amended claims .

10. The previously pending rejection of claims 1,2,4,5 under 35 U.S.C. 103(a) as being unpatentable over Ashkenazi et al. (US 2006/0073146) in view of Seol et al. (US 2002/0128438) in view of Frischholz et al. is withdrawn in view of the amended claims and cancellation of claims 4 and 5.

11. The previously pending rejection of claims 3,6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Ashkenazi et al. (US 2006/0073146) in view of Seol et al. (US 2002/0128438) in view of Frischholz et al. as applied to claims 1,2,4,5 above, and further in view of Rixon et al. (US 2003/0103986) is withdrawn in view of the amended claims and cancellation of claims 6 and 7.

12. Claims 1,2,9,18,20,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashkenazi et al. (US 2006/0073146) in view of Tai et al..
Ashkenazi et al. teach TACI extracellular domain fused to a leucine zipper (see [0123]). Ashkenazi et al. teach that the leucine zipper used can mediate trimerization (see [0149]). TACI extracellular domain/leucine zipper trimerization peptide fusion proteins would form trimers via the trimerization domain. Ashkenazi et al. do not teach the use of the trimerizing fragment of Heat Shock Binding Protein-1 (HSBP-1). Tai et al. teach that HSBP-1 has a trimerizing domain and the amino acid sequence recited in claim 22 (see abstract and Figure 1). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Ashkenazi et al. teach TACI extracellular domain fused to a trimerization domain whilst Tai et al. teach that HSBP-1 has a trimerizing domain and the amino acid sequence recited in claim 22. One of ordinary skill in the art would have been motivated to do the aforementioned because Ashkenazi et al. teach TACI extracellular domain trimers formed by a trimerization domain whilst Tai et al. teach that HSBP-1 has a trimerizing domain. Furthermore, in KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that **"if a technique has been used to improve**

**one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill"**. Ashkenazi et al. disclose that said TACI fusion proteins can be produced in mammalian cells (see [0096] and [0103]). The fusion protein can have a polyhistidine tag (see [0150]). Ashkenazi et al. teach TACI extracellular domain fused to a leucine zipper (see [0123]). Ashkenazi et al. teach that the leucine zipper used can mediate trimerization (see [0149]). TACI extracellular domain/leucine zipper trimerization peptide fusion proteins would form trimers via the trimerization domain. The fusion proteins would have the functional properties recited in the claims because they are the same molecules as recited in the claims.

13. Claims 3,10,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashkenazi et al. (US 2006/0073146) in view of Tai et al. as applied to claims 1,2,9,18,20,21 above and further in view of Rixon et al. (US 2003/0103986).

The previous rejection renders obvious the claimed peptide except for use of the peptide of claim 3, part (1). Rixon et al. teach the TACI extracellular domain containing amino acids 30 to 110 of SEQ ID No:4 (see [0021]). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous rejection renders obvious the claimed peptide except for use of the peptide of claim 3, part (1) whilst Rixon et al. teach the TACI extracellular domain containing amino acids 30 to 110 of SEQ ID No:4. One of ordinary skill in the art would have been motivated to do the aforementioned because Ashkenazi et al. teach TACI extracellular domain fused to a trimerizing peptide and that art known TACI extracellular domains can be used in their TACI extracellular domain/leucine zipper fusion proteins.

14. No claim is allowed

15. Applicant's amendment and submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 4/18/07 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**

**ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron, Ph.D./
Primary Examiner, Art Unit 1644